IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
GREENVILLE DIVISION

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| Forlondona Hill, individual, as Personal Representative of the Estate of Bobby Louis Hill,<br><br>Plaintiff,<br><br>v.<br><br>Abbott Laboratories; St. Jude Medical, Inc.; St. Jude Medical, LLC; St. Jude Medical S.C., Inc.; Pacesetter, Inc., d/b/a St. Jude Medical Cardiac Rhythm Management Division; and John Doe,<br><br>Defendants. | ) | C/A No. 6:19-cv-01011-DCC<br><br><br><br>**OPINION AND ORDER** |

This matter comes before the Court on Defendants Abbott Laboratories, St. Jude Medical, Inc.,[1] St. Jude Medical S.C., Inc. and Pacesetter, Inc.'s (collectively, "St. Jude Defendants") Motion to Dismiss. ECF No. 66. Plaintiff filed a Response in Opposition, and the St. Jude Defendants filed a Reply. ECF Nos. 69, 70. Therefore, the Motion is ripe for review.

## BACKGROUND[2]

Plaintiff filed this case in the Court of Common Pleas for Greenville County, South Carolina, alleging a variety of claims against Defendants related to the manufacture, marketing, sale, and distribution of an allegedly defective, adulterated, and recalled St.

[1] St. Jude Medical, LLC is the successor to St. Jude Medical, Inc., and has not separately appeared in the case.

[2] In light of the procedural posture of this case, the factual allegations are taken from Plaintiff's Complaint.

Jude Fortify Assura implantable cardiac defibrillator ("ICD") – Model Number CD2357-40Q, serial number 7098096 ("the Device"). Plaintiff contends that the Device contains a battery depletion defect ("the Defect"), which caused rapid battery depletion on the day of Mr. Hill's death. ECF No. 1-1. Defendants filed a Notice of Removal, contending that this Court has subject matter jurisdiction under 28 U.S.C. § 1332. ECF No. 1. The St. Jude Defendants filed a Motion to Dismiss, ECF No. 9, and Plaintiff filed a Consent Motion to Amend her Complaint, ECF No. 17. The Court granted the Consent Motion, ECF No. 18, and Plaintiff filed an Amended Complaint, ECF No. 21.

After Plaintiff filed an Amended Complaint, the St. Jude Defendants again filed a Motion to Dismiss.[3] ECF No. 27. Additionally, the St. Jude Defendants filed a Request for Judicial Notice, asking the Court to take judicial notice of two Premarket Approval ("PMA") letters from the Food and Drug Administration ("FDA"). ECF No. 28. Plaintiff filed a Response in Opposition to the St. Jude Defendants' Motion to Dismiss, and the St. Jude Defendants filed a Reply. ECF Nos. 32, 36. The Court held a hearing on the Motion on February 28, 2020. At the hearing, the Court granted the Request for Judicial Notice, with the consent of all parties, and took the Motion under advisement. ECF No. 50.

Following the hearing, Plaintiff filed a Motion to Amend, seeking leave to file a Second Amended Complaint. ECF No. 52. The St. Jude Defendants filed a Response in Opposition, and Plaintiff filed a Reply. ECF Nos. 56, 59. The Court entered an Order

[3] At the time, there were three other Defendants in the case—Great Batch, Inc., GreatBatch Ltd., and Integer Holdings. These Defendants also filed a Motion to Dismiss. ECF No. 30. These Defendants have now been dismissed from the case. ECF No. 54.

granting Plaintiff's Motion to Amend, finding that "Plaintiff's proposed amendment would not be futile." ECF No. 61. On March 31, 2020, Plaintiff filed a Second Amended Complaint, which is the operative pleading before the Court. ECF No. 63.

Plaintiff's Second Amended Complaint contains a wrongful death and survival action, and contains detailed allegations about the Device, the Defect, and Mr. Hill's death. Generally, Plaintiff contends that the St. Jude Defendants designed, manufactured, marketed, and sold an ICD that is "surgically placed in a patient's body to treat irregular heart rhythms, known as arrhythmias." ECF No. 63 at 11. "ICDs operate by using electrical pulses or shocks to control life-threatening arrhythmias." *Id.* These ICDs are powered by lithium batteries and "were designed with battery chemistry that provides for enhanced or extended longevity." *Id.* at 12. "In 2004, St. Jude Medical received [PMA] to market" its first ICD. *Id.* at 13. "Since then, St. Jude Medical has designed, manufactured, marketed, and sold several models of ICDs," including the Device at issue in this case. *Id.*

Plaintiff alleges that the St. Jude Defendants' ICD devices, including the Device in this case, had a critical defect. *Id.* at 24. "Deposits of lithium, known as lithium clusters, can form within the battery and create abnormal electrical connections that cause the battery to short circuit which leads to rapid battery failure." *Id.* at 24 (internal quotation marks omitted). In theory, the ICD devices were "designed to deliver a gentle vibratory alert to patients when the battery is nearing its end of life." *Id.* at 23. However, "because the battery depletion could occur rapidly, some patients, like Mr. Hill, were unable to detect the device alert before full battery drainage." *Id.* at 24.

Plaintiff contends that the St. Jude Defendants received reports about the Defect as early as 2011. *Id.* Despite learning about the nature of the defect in December 2014 and directing the battery manufacturer to "implement a design improvement," the St. Jude Defendants failed to notify the FDA until 2016. *Id.* at 25. On October 10, 2016, the FDA issued a Class I Recall ("the Recall") of more than 250,000 ICDs manufactured by the St. Jude Defendants on or before May 2015 because of the Defect. *Id.* Unfortunately, Mr. Hill had been dead for fifteen months at the time of the Recall. *Id*. at 28.

Mr. Hill had heart surgery in 2011, during which a pacemaker was implanted. *Id.* at 36. On October 3, 2014, Mr. Hill's pacemaker was replaced with the Device. *Id.* Many of the St. Jude Defendants' ICDs had malfunctioned due to the Defect by the time the Device was implanted into Mr. Hill's body. *Id.* On July 11, 2015, Mr. Hill "suffered four cardiac events and four silent heart attacks." *Id.* at 37. "On each occasion of the said cardiac events, [the Device], due to [the Defect], failed to operate as intended by providing life-saving pacing and shock therapy to Mr. Hill." *Id.* Mr. Hill was transported by EMS to the Emergency Room at Greenville Memorial Hospital, where he suffered a final, fatal cardiac event because the Device's battery had fully drained. *Id.* "A physician noted in Mr. Hill's medical records, but did not advise Mr. Hill's family, that the ICD implanted into Mr. Hill never went off." *Id.* at 38.

Plaintiff raises eight claims: (1) Breach of Express Warranty (Survival and Wrongful Death); (2) Breach of Implied Warranty (Survival and Wrongful Death); (3) Negligence (Survival and Wrongful Death); (4) Failure to Warn (Survival and Wrongful Death); (5) Product Liability - Manufacturing Defect (Survival and Wrongful Death); (6) Strict Liability

- Manufacturing Defect (Survival and Wrongful Death); (7) Misrepresentation by Omission (Survival and Wrongful Death); and (8) Unjust Enrichment (Survival and Wrongful Death). ECF No. 63. In response, the St. Jude Defendants filed a Motion to Dismiss Plaintiff's Second Amended Complaint. ECF No. 66. Plaintiff filed a Response in Opposition, and the St. Jude Defendants filed a Reply. ECF No. 69, 70. Therefore, the matter has been fully briefed and is ripe for the Court's review.

**LEGAL STANDARD**

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits the dismissal of an action if the complaint fails "to state a claim upon which relief can be granted." Such a motion tests the legal sufficiency of the complaint and "does not resolve contests surrounding the facts, the merits of the claim, or the applicability of defenses . . . . Our inquiry then is limited to whether the allegations constitute 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Republican Party of N.C. v. Martin*, 980 F.2d 943, 952 (4th Cir. 1992) (internal quotation marks and citation omitted). In a Rule 12(b)(6) motion, the court is obligated to "assume the truth of all facts alleged in the complaint and the existence of any fact that can be proved, consistent with the complaint's allegations." *E. Shore Mkts., Inc. v. J.D. Assocs. Ltd. P'ship*, 213 F.3d 175, 180 (4th Cir. 2000). However, while the Court must accept the facts in a light most favorable to the nonmoving party, it "need not accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Id*.

To survive a motion to dismiss, the complaint must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570(2007). Although the requirement of plausibility does not impose a probability

requirement at this stage, the complaint must show more than a "sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint has "facial plausibility" where the pleading "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

## DISCUSSION

### I. Statute of Limitations on Wrongful Death Claim

Mr. Hill died on July 11, 2015, and Plaintiff did not file a Complaint until March 4, 2019—three years, seven months, and 21 days after his death. ECF No. 32 at 11. Initially, in response to the St. Jude Defendants' Motion to Dismiss Plaintiff's First Amended Complaint, Plaintiff contended that Section 62-3-109 of the South Carolina Code tolled the three-year statute of limitations for eight months following Mr. Hill's death. *Id.* The Court rejects this argument for the reasons set forth during the prior hearing, as the eight-month tolling period applies to claims that accrue *prior* to the decedent's death. Here, the wrongful death cause of action accrued upon his death.

In the Second Amended Complaint, Plaintiff now invokes the discovery rule and an estoppel theory to argue that she did not discover the Defect until after an October 10, 2016 FDA recall of the Device. ECF No. 63. To that end, Plaintiff contends that she "could not have reasonably discovered [the Defect] while Defendants were actively concealing, failing to disclose and shielding from public knowledge, the true degree of risks associated with [the Device]." *Id.* at 4. In response, the St. Jude Defendants contend that the discovery rule does not apply to wrongful death cases and further contend that Plaintiff should reasonably have known about the Device's failure due to Plaintiff's admission that the treating physician noted the failure in the medical records.

ECF No. 70 at 18. In light of the procedural posture of the case, the Court finds that Plaintiff has plausibly pled a wrongful death cause of action under South Carolina law. The Court need not reach the issue of whether the discovery rule applies, as Plaintiff has plausibly pled equitable estoppel or tolling of the statute of limitations. *See, e.g., Hooper v. Ebenezer Senior Servs. & Rehab. Ctr.*, 687 S.E.2d 29, 32 (2009) ("It has been observed that '[e]quitable tolling typically applies in cases where a litigant was prevented from filing suit because of an extraordinary event beyond his or her control.'" (quoting *Ocana v. Am. Furniture Co.*, 135 N.M. 539, 91 P.3d 58, 66 (2004))). Plaintiff has plausibly pled that the St. Jude Defendants actively concealed the nature of the Defect, which led to a delay in filing this case. Accordingly, dismissal at this stage of the proceedings would be improper.

Discovery in this case may ultimately reveal that Plaintiff should have reasonably learned about the Defect at an earlier time; however, that is an issue to be determined at the summary judgment stage or by a jury if Plaintiff raises a genuine issue of material fact. Accordingly, Plaintiff has pled timely causes of action under both a wrongful death and survival theory.

## II. Preemption

The St. Jude Defendants claim that Plaintiff's claims are preempted, as she fails to plead a parallel claim. Thus, they argue that the failure to identify a specific PMA requirement that was violated and imposes a duty that is identical to state law is fatal to each of her claims in the Second Amended Complaint.

In 1976, Congress passed the Medical Device Amendments ("MDA") in order to impose detailed federal oversight to govern medical devices." *Walker v. Medtronic, Inc.*,

670 F.3d 569, 572 (4th Cir. 2012). "To that end, the MDA includes a provision expressly preempting state regulation of medical devices." *Id.* It states in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). "The MDA also establishes three classes of medical devices, organized according to the level of oversight required to ensure their safety." *Walker*, 670 F.3d at 572. "Class III devices require the highest level of federal oversight," and the Device in this case is a Class III device. *Id.* "Because of the risks associated with them, Class III devices are required to go through [PMA] 'to provide reasonable assurance of [their] safety and effectiveness.'" *Id.* (quoting 21 U.S.C. § 360c(a)(1)(C)).

PMA is a rigorous process. *Id.* To obtain PMA, "a device manufacturer must submit to the FDA full reports of all investigations relating to the device's safety or effectiveness; a full statement of the components, ingredients, and properties and of the principle or principles of operation of the device, a full description of the manufacturing methods and the facilities and controls used for the device's manufacturing; references to any performance standards applicable to the device; samples of the device and any component parts; examples of the proposed labeling for the device; and other information as requested." *Id.* at 572–73 (citing 21 U.S.C. § 360e(c)(1)) (internal quotations omitted).

Given the extensive regulation of Class III medical devices and the preemption in the MDA, the Supreme Court has offered guidance on what claims survive the MDA's

express preemption clause. In *Riegel v. Medtronic*, "the Supreme Court considered whether a plaintiff's common law claims based on the failure of a Class III medical device were precluded by the MDA's express preemption clause, which preempts state requirements 'different from, or in addition to' requirements applicable under federal law." *Id.* at 577 (citing *Riegel v. Medtronic*, 552 U.S. 312, 321 (2008)) (quoting 21 U.S.C. § 360k(a)(1)). To resolve this question, the Court undertook a two-part inquiry. *Id*. at 321–22. First, the Court examined whether the federal government established requirements applicable to the device. *Id.* at 321. The Court determined that, because Class III devices are required to undergo the PMA process, this first requirement is met in regard to all Class III devices. *Id.* Second, the Court considered whether the state common law claims imposed requirements that were different from or in addition to the federal requirements and "relate[d] to the safety or effectiveness of the device or to any other matter included in a requirement of the device." *Id.* at 323.

"In sum, the Supreme Court held that the terms of a Class III device's [PMA] constitute federal requirements and that a common law tort claim premised on different or additional requirements is preempted by the MDA." *Walker*, 670 F.3d at 577. "The Supreme Court did recognize one situation in which a plaintiff's common law claims would not be preempted under the MDA: when 'state duties . . . parallel, rather than add to, federal requirements.'" *Id*. (quoting *Riegel*, 552 U.S. at 330) (internal quotation marks omitted). "This situation occurs when claims are 'premised on a violation of FDA regulations.'" *Id.* (quoting *Riegel*, 552 U.S. at 330). With this guidance in mind, the Court turns to Plaintiff's claims in this case.

### A. Breach of Express and Implied Warranty Claims

The St. Jude Defendants first contend that "Plaintiff has made ***no attempt*** to plead a parallel claim to save her express and implied warranty claims from preemption—much less to identify a specific PMA requirement that has been violated—and her claims fail for this reason alone." ECF No. 66-1 at 10. After reviewing Plaintiff's claims, the Court agrees that Plaintiff's express and implied warranty claims are preempted.

As to her express warranty claims, Plaintiff largely argues that the Device did not perform in compliance with a product manual distributed by the St. Jude Defendants. *See* ECF No. 63 at 46. Additionally, Plaintiff alleges that the Device was not "adequately packaged, labeled, promoted, or fit for the ordinary purposes for which such devices are used." These are precisely the type of claims that *Riegel* finds are preempted by the MDA, as the express warranty claim "would impose a standard different from, or in addition to, the FDA's safety and efficacy determination" in the PMA. ECF No. 66-1 at 11.

As to the implied warranty claim, Plaintiff claims that the St. Jude Defendants assured Plaintiff that the Device "was of merchantable quality, safe, fit, and effective for its intended use." ECF No. 63 at 49. Again, this requirement seeks to impose requirements that are different from or in addition to the requirements the FDA made in the PMA process. This claim, and the express warranty claim, directly or indirectly challenge the adequacy of the FDA's determinations made during the PMA process and are the type of claims preempted by the MDA. Accordingly, Plaintiff's First and Second Cause of Action are DISMISSED.

**B. Negligence and Manufacturing Defect Claims**

The St. Jude Defendants next contend that Plaintiff's Negligence and Manufacturing Defect Claims are preempted because her parallel claims are "invented from whole cloth." ECF No. 66-1 at 12. The Court disagrees.

Plaintiff's negligence claim alleges, *inter alia*, that the St. Jude Defendants "breached their duty to Mr. Hill by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of [the Device]." *Id.* at 52. Similarly, Plaintiff's manufacturing defect claim alleges that the Device contained the Defect, which "differed from the design specifications and requirements of the said device as set forth in the PMA and the FDA's conditions for approval." ECF No. 63 at 56.

While the Court agrees with the St. Jude Defendants' argument that Plaintiff's reliance on the FDA's 2017 Warning Letter is insufficient, in and of itself, to prove a violation of federal law sufficient to prove a parallel claim, this case is at the Motion to Dismiss stage and the St. Jude Defendants have the burden of proving preemption. Plaintiff has alleged state law causes of action for negligence and manufacturing defects, which specifically contend that the St. Jude Defendants' conduct violated the PMA and federal law. As Plaintiff points out, "allegations that the defendant violated [PMAs], so long as they are supported by sufficient factual evidence and demonstrate a causal connection to the alleged injuries, are all that is required to satisfy *Twombly* and avoid preemption under § 360k and *Riegel*." *Connelly v. St. Jude Medical, Inc.*, No. 5:17-cv-02006-EJD, 2017 WL 3619612, at *3 (N.D. Cal. Aug. 23, 2017) (quoting *Rosen v. St. Jude Med. Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014)). Indeed, the Second Amended

Complaint contains ample factual information to support a plausible inference that the St. Jude Defendants violated the PMA and federal law. That is not to say that Plaintiff will prevail; however, she should have the opportunity to conduct discovery to determine what the PMA's requirements are and whether the St. Jude Defendants complied with those requirements. Accordingly, the St. Jude Defendants' Motion to Dismiss Plaintiff's Third, Fifth, and Sixth Causes of Action on the basis of preemption is DENIED.

**C. Failure to Warn and Misrepresentation by Omission**

Defendants next contend that Plaintiff's failure to warn and misrepresentation by omission claims are preempted by the MDA. In response, Plaintiff argues that the St. Jude Defendants "had continuing obligations under the PMA Supplement and federal regulations, which the FDA found it violated; and its failure to comply with the regulations resulted in its failure to warn the recipients of the ICD of the hazardous situation." ECF No. 69 at 18. Again, the Court finds that Plaintiff has alleged a sufficient factual basis to lead to the plausible inference that the St. Jude Defendants violated state law in a manner that did not impose requirements in addition to or different from federal law. As Plaintiff notes, it is plausible that, "had St. Jude Medical not concealed the hazardous defect, either the adulterated ICD would not have been implanted into Mr. Hill, or he would have been warned of the hazard before the malfunction and his resulting death." ECF No. 69 at 20. As pled, the failure to warn and misrepresentation by omission claims are premised on FDA findings that the St. Jude Defendants violated their federal obligations. Accordingly, the St. Jude Defendants' Motion to Dismiss Plaintiff's Fourth and Seventh Causes of Action on the basis of preemption is DENIED.

### D. Unjust Enrichment

Finally, Defendant argues that Plaintiff's unjust enrichment cause of action does not contain a parallel claim and instead is based on the allegation that the Device "was not safe for use." ECF No. 66-1 at 16 (quoting ECF No. 63 at 62). The Court agrees and finds that this cause of action is barred by the MDA as it seeks to impose requirements in addition to, or different from, those under federal law. Accordingly, Plaintiff's Eighth Cause of Action is dismissed.

## III. Plausibility of Plaintiff's Allegations

The St. Jude Defendants also argue that Plaintiff's claims do not meet the requisite federal pleading standards. As set forth above, the Court has dismissed Plaintiff's Breach of Express Warranty, Breach of Implied Warranty, and Unjust Enrichment causes of action. Accordingly, the Court limits its discussion to the remaining causes of action.

### A. Negligence, Manufacturing Defect, and Failure to Warn

The St. Jude Defendants contend that Plaintiff's Negligence, Manufacturing Defect, and Failure to Warn claims are too conclusory. However, as detailed above, the Court finds that Plaintiff has pled facts sufficient to state plausible parallel claims under *Riegel*. The issues of causation and specific deviations from the PMA are questions to be resolved after discovery—either at summary judgment or by a jury. Accordingly, the St. Jude Defendants' Motion is DENIED as to these claims.

### B. Misrepresentation by Omission

Although Plaintiff's Misrepresentation by Omission claim is subject to Federal Rule of Civil Procedure 9(b)'s heightened pleading requirement, the Court again finds that Plaintiff has pled very specific allegations of wrongdoing that do not run afoul of the MDA

and *Riegel*. Considering Plaintiff's inability to review the PMA, the Court finds that the factual allegations are sufficient to allege with particularity the federal requirements that the St. Jude Defendants violated. *See* ECF No. 63 at 59. Accordingly, the St. Jude Defendants' Motion to Dismiss this claim is DENIED.

## IV. Propriety of Abbott Laboratories as a Defendant

Finally, the St. Jude Defendants argue that Defendant Abbott Laboratories "should be dismissed from this case because it had no role regarding [the Device] from October 2014 (the date of implant) to July 2015 (when Decedent passed away), and it is not a successor-in-interest to the entity that did (St. Jude Medical, Inc.)." ECF No. 66-1 at 25 (quotation omitted). Plaintiff responds by claiming that the Second Amended Complaint "details the relationship between Abbott Laboratories and St. Jude" and the "continuity of the business enterprise." ECF No. 69 at 38. While the St. Jude Defendants' position may ultimately prove to be correct, the Court finds that dismissal at this early stage of the proceedings is inappropriate.

## CONCLUSION

For the foregoing reasons, the St. Jude Defendants' Motion to Dismiss, ECF No. 66, is **GRANTED IN PART and DENIED IN PART.** Specifically, Plaintiff's First, Second, and Eighth Causes of Action are **DISMISSED WITH PREJUDICE**. Plaintiff has had three opportunities to plead permissible parallel claims; accordingly, the Court finds that amendment would be futile.

IT IS SO ORDERED.

**s/ Donald C. Coggins, Jr.**
United States District Judge

August 19, 2020
Spartanburg, South Carolina